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# The Implementation of FDA Determinations in Litigation - Why Do We Defer to the PTO but Not to the FDA?

William G. Childs

*Western New England University School of Law*, [wchilds@law.wne.edu](mailto:wchilds@law.wne.edu)

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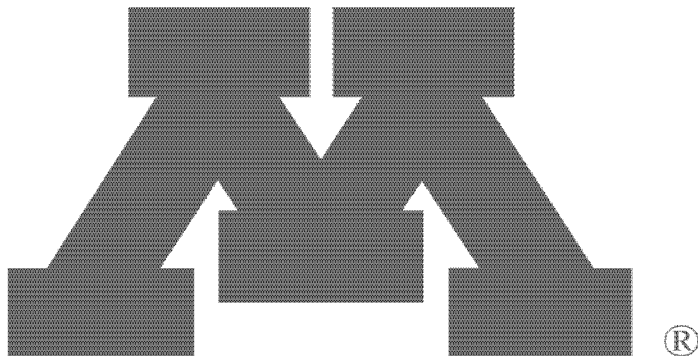
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## **The Implementation of FDA Determinations in Litigation: Why Do We Defer to the PTO but Not to the FDA? \***

**William G. Childs\*\***

In early 1987, a scientist working in the research laboratories of MegaPharma Co., a pharmaceutical company, discovered a molecule that she believed would be an effective treatment for depression. Early preclinical work was promising. Therefore, her company's patent lawyers filed an application in her name in late 1987 for a patent to be assigned to the company.

The prosecution of the patent lasted for twenty-one months, and the prosecution history came to fill close to half a banker's box. The patent examiner focused on three pieces of prior art that he initially suggested might render the claimed invention obvious. After correspondence was exchanged on this topic of obviousness, the examiner became convinced that the molecule was, in fact, a patentable invention – that it was useful, new, obvious, and enabled.<sup>1</sup> The patent issued in 1989. The patent prosecution process, excluding the actual discovery of the molecule, took approximately eighty hours of work by the inventor and MegaPharma's inside patent counsel, and about twenty hours by the patent examiner.

Meanwhile, MegaPharma decided the molecule, a member of the class of drugs known as selective serotonin reuptake in-

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\*\* Assistant Professor (as of August 2004), Western New England College School of Law. Thanks to Mark Lemley and David Anderson for their comments on drafts, and to audiences at the Western New England College School of Law, the University of Cincinnati College of Law, the University of South Carolina School of Law, and the Northern Illinois University College of Law. Thanks also to the editors at the *Minnesota Intellectual Property Review* for their thoughtful comments and editing. Errors naturally remain mine. I acknowledge the support of Williams & Connolly LLP in preparing this article. This article does not necessarily reflect the views of either Williams & Connolly or its clients. I am grateful to Dena, Ella, and Liam Childs for their support and patience.

<sup>1</sup> See 35 U.S.C. §§ 101 (utility), 102 (novelty), 103 (non-obviousness), & 112 (enablement) (2000); see generally *Graham v. John Deere*, 383 U.S. 1 (1966).

hibitors (“SSRIs”), had the potential to make a splash in the multi-billion dollar market for safe and effective treatments for depression. Though there were several other SSRIs already on the market, MegaPharma’s marketing department concluded that the drug would fit into a small but profitable niche, serving as the “cost-effective SSRI”. Accordingly, the company’s management approved the drug’s development.

The preclinical work began in early 1988, and consisted of standard *in vitro* and *in vivo* studies considering toxicity, absorption, metabolism, and excretion.<sup>2</sup> These early studies provided a foundation of information from which later trials would be developed. The company decided, based on these early results, to file an Investigational New Drug application (“IND”).<sup>3</sup> The IND provides the Food and Drug Administration (“FDA”) with a pharmacological profile of the drug, results of acute toxicology studies in at least two species of animals, and the results of short-term toxicity studies.<sup>4</sup> The FDA did not oppose the IND within thirty days, and it was thus approved in early 1991.<sup>5</sup>

The first Phase I and Phase II clinical trials began shortly thereafter. Phase I trials, with twenty to eighty healthy volunteers, are used to evaluate safety, to further determine a dosage range, and to identify side effects.<sup>6</sup> Phase II trials, commencing somewhat later, include between one and three hundred participants, and help determine the medicine’s efficacy and provide further data on its safety.<sup>7</sup>

The data from these Phase I and II trials raised no significant concerns with respect to the medicine’s safety profile, though they confirmed that, as with other SSRIs, the medicine seemed to cause headaches and tremor. The data also indicated an efficacy profile similar to other SSRIs. Thus, with preclinical data and data from the Phase I and II clinical trials,

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<sup>2</sup> See FDA, *The Beginnings: Laboratory and Animal Studies*, <http://www.fda.gov/cder/about/whatwedo/testtube-3.pdf> (last visited Dec. 15, 2003).

<sup>3</sup> See Center for Drug Evaluation and Research, *Frequently Asked Questions on Drug Development and Investigational New Drug Applications*, <http://www.fda.gov/cder/about/smallbiz/faq.htm> (last visited June 2, 2003).

<sup>4</sup> See *id.*

<sup>5</sup> See Center for Drug Evaluation and Research, *supra* note 3.

<sup>6</sup> See National Library of Medicine, *ClinicalTrials.gov, Linking Patients to Medical Research*, <http://www.clinicaltrials.gov/ct/info/whatis> (last visited June 2, 2003).

<sup>7</sup> See *id.*

MegaPharma's scientists were approved to go forward with Phase III trials. Phase III trials involve much larger populations, one to three thousand volunteers, and research further the drug's safety and efficacy.<sup>8</sup>

At this point, the drug was named Phelox for marketing purposes. It was ultimately tested in eight thousand patients, a number comparable to other SSRI clinical trials. As with the Phase I and Phase II trials, no significant issues were identified from a safety perspective; and Phelox appeared to be comparable to other SSRIs in its efficacy. Based on this data, MegaPharma filed a New Drug Application ("NDA"), seeking the FDA's permission to market Phelox for the treatment of depression.

Phase III trials indicated that a slightly higher percentage of people taking Phelox experienced tremor than those taking placebo or comparator SSRIs. However, this difference was not statistically significant. Neither MegaPharma nor the FDA considered the difference to be of importance and, after eight years of preclinical and clinical trials, Phelox was approved for marketing in 1999. Phelox's label, as agreed upon with the FDA, contained a warning regarding tremor as a side effect of the class of SSRIs, including Phelox. However, the labeling did not indicate, nor did MegaPharma believe, that it occurred any more often with Phelox than with other SSRIs.

The preclinical and clinical research involved thousands of hours of work by MegaPharma employees. Furthermore, hundreds of hours of work by a team of FDA scientists and doctors were required for FDA approval. In the end, Megapharma spent almost \$500 million in development costs.

MegaPharma launched an aggressive marketing campaign in support of Phelox, emphasizing its low cost and its appropriateness for patients without insurance. The marketing efforts included a substantial direct-to-consumer component, including television advertisements urging patients to seek treatment for depression and trumpeting Phelox's relatively low price. Its efforts paid off quickly, as the medicine rapidly achieved a five percent market share that continued to grow consistently.

MegaPharma's success received the attention of a small generic drug company, GenerDrugs. In early 2003, GenerDrugs decided that the three pieces of prior art considered important by the patent examiner rendered Phelox obvious. Con-

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<sup>8</sup> See *id.*

sequently, it submitted an Abbreviated New Drug Application ("ANDA"), as provided by the Hatch-Waxman Act.<sup>9</sup> As part of this ANDA, GenerDrugs included what is known as a "Paragraph IV" certification that the brand name company (*i.e.*, MegaPharma) held no valid patents that were infringed by the proposed generic equivalent of Phelox.<sup>10</sup> MegaPharma promptly filed suit against GenerDrugs for patent infringement.

At the same time that the generic drug company decided it was interested in Phelox, so, too, did a group of Mississippi plaintiffs' lawyers who specialized in lawsuits against pharmaceutical companies. An article published in a peer-reviewed medical journal noted that an HMO had examined its members' data on various SSRIs. The efficacy data for Phelox was comparable to those for other SSRIs. However, the lawyers noticed in the adverse event data that substantially more Phelox patients complained of tremor than patients taking other SSRIs. At the same time, an article was published in a second medical journal that provided theoretical support for a link between SSRIs and Parkinson's disease, noting in particular that tremor is a possible early warning sign of Parkinson's.

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<sup>9</sup> Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 202, 98 Stat. 1585, 1603 (codified at 15 U.S.C. §§ 68b-68c, 70b (1994); 21 U.S.C. §§ 301 note, 355, 360cc (1994); 28 U.S.C. § 2201 (1994); 35 U.S.C. §§ 156, 271, 282 (1994)) [hereinafter Hatch-Waxman Act].

<sup>10</sup> The Hatch-Waxman Act provides for this approach when a generic company believes that a patent involving a brand-name drug is either not infringed by the generic or not valid. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2000). The Paragraph IV certification puts the brand-name company on notice of the generic drug company's intent to make a bioequivalent drug, and creates federal jurisdiction for a lawsuit against the generic manufacturer. See *id.* If the brand-name company files suit within forty-five days, the FDA approval is stayed for thirty months. See § 355(j)(5)(B)(iii). At the end of the process, if the generic drug manufacturer obtains the right to market the drug, it will have a 180-day exclusivity period. See § 355(j)(5)(B)(iv).

Despite the fact that most patent infringement suits carry a jury right, there is no established right to a jury trial when suit is brought under the Hatch-Waxman Act. See Brian D. Coggio & Sandra A. Bresnick, *The Right to a Jury Trial in Actions Under the Waxman-Hatch Act*, 52 FOOD & DRUG L.J. 259, 275 (1997). It is not clear whether a judge could permit a jury trial if requested by the parties. It is also not clear whether the lack of a jury right would be upheld if constitutionally challenged. Thus, the hypothetical is in some sense fictional as it would be extremely uncommon for a generic drug dispute to be tried before a jury. The presumption of validity certainly still applies when the issue is tried to a judge. This minor fiction is not particularly important, as most patent litigation remains in front of juries, and the hypothetical provides a useful way to compare directly the value of the agency actions in question.

The Mississippi lawyers moved into action, rapidly signing up plaintiffs through television and newspaper ads suggesting that Phelox patients “may be at an increased risk of Parkinson’s disease – and MegaPharma should pay.” Hundreds of plaintiffs, some with Parkinson’s and many without, signed up within weeks, and the first lawsuit was filed two weeks after the articles appeared.

MegaPharma thus faced a situation where it had what can colloquially be referred to as two government licenses, one to exclude others from using its molecule and one to sell the medicine containing that molecule as “safe and effective.” It also faced two close-call cases, where its attorneys advised that the odds were roughly even that a jury would find either its patent invalid or its drug to be unsafe. What do these licenses get MegaPharma?

Its patent gets MegaPharma a presumption of validity, such that the accused infringer must prove invalidity by clear and convincing evidence.<sup>11</sup> The accused infringer can also prove the patent unenforceable if it can show inequitable conduct, once again by clear and convincing evidence.<sup>12</sup> On the other hand, in the tort litigation, MegaPharma gets an opportunity to tell the jury about the FDA’s approval. However, Megapharma gets no presumption, no increased burden of proof, nor an instruction that FDA approval should be considered as relevant in determining design, marketing defect, or assessing punitive damages.

This article examines the possible inequity of the treatment of licensees’ rights in tort litigation in comparison to patent rights in patent litigation. In particular, this article presents the presumptions afforded from issued patents as a valid model for the proper treatment of FDA approval in litigation. Presently, most academic discussion proposes either preclusion of tort claims or leaving the system more or less as it stands. This article, on the other hand, proposes a middle ground.

This article begins by examining the differences between the USPTO and the FDA. In particular, the quantity and quality of the review provided by each agency is explored along with the purposes of that review. The article then turns to a more complete examination of how a patent or FDA approval is

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<sup>11</sup> See, 35 U.S.C. § 282 (2000); *see also, e.g.*, *Neff Instrument Corp. v. Cohu Elecs., Inc.*, 298 F.2d 82, 86 (9th Cir. 1961).

<sup>12</sup> See *Goodyear Tire & Rubber Co. v. Hercules Tire & Rubber Co.*, 162 F.3d 1113, 1122 (Fed. Cir. 1998).

treated in litigation, both in principle and in practice. The advantages to the patent-holder include evidentiary presumptions as well as instructions from the judge regarding those presumptions.

With the factual scenario and the differences in treatment established, this article next looks to why the treatments of the agency determinations in question differ in these contexts. Presently, the patent holder is positioned to benefit from USPTO mistakes (*i.e.*, an erroneous grant of a patent) more than the manufacturer of an FDA-approved medicine will benefit from an FDA mistake (*i.e.*, approval of an unsafe or ineffective drug). In other words, in a comparably close case (as the hypothetical case above is intended to represent), a patent holder will win while a holder of an FDA approval will lose.

A determination of whether this difference in advantages is appropriate can be made only through examination of the interests at issue. As an initial matter, this article examines government interests including ensuring that determinations made by the USPTO or FDA are accurate and implemented appropriately. Also examined are the individual and societal interests furthered by patent litigation and product liability litigation. In patent litigation, courts seek to protect proper patent monopolies while preventing improper ones (*i.e.*, those based on invalid or unenforceable patents). In the pharmaceutical context, courts seek to protect citizens from unsafe drugs while avoiding imposing unwarranted liability on drug producers. Whether these interests are, or are not, furthered through a variety of procedural mechanisms is a critical matter when determining if those mechanisms are appropriate.

After exploring the USPTO and FDA in comparison to each other, this article lays out the present posture of the debate on how to treat FDA approval in litigation. The bulk of discussion can be categorized into two areas: one urging preclusion of tort liability if the defendant complied with relevant regulatory requirements and another opposing such preclusion and leaving the system as it stands, with some incremental institutional changes.

Concluding remarks demonstrate that a juxtaposition of the USPTO and FDA processes indicates that FDA approval should receive at minimum the deference in litigation that an issued patent receives. Therefore, this article proposes a presumption of safety and efficacy for FDA-approved drugs. With the outlines of the proposed presumption established, the arti-



cle further considers the presumption in the context of the concerns raised by the various commentators in the regulatory compliance defense debate. Finally, the article concludes that a presumption from FDA licensing addresses these concerns better than the proposals made by commentators to date.<sup>13</sup>

## I. HOW PATENTS ARE GRANTED (OR AREN'T) AND HOW FDA APPROVALS ARE GRANTED (OR AREN'T)

### A. PATENT ISSUANCE

By its own terms, “[t]he role of the USPTO is to grant patents for the protection of inventions.”<sup>14</sup> In 2001, 345,732 applications were received by the USPTO and 183,975 patents were granted.<sup>15</sup> At the same time, the USPTO has roughly 3,500 patent examiners.<sup>16</sup> Thus, each examiner reviews roughly 50 patents per year, or one patent per week.

The patent process begins, unsurprisingly, with a patent application.<sup>17</sup> This document, typically 50 to 100 pages long,

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<sup>13</sup> Although it is not central to this article, the argument presented would support a conclusion that the treatment of the respective agencies' decisions should in fact be reversed; the presumption of validity should be eliminated while a presumption of safety and efficacy should be implemented. The implications of this article in the patent context will have to be fully explored another day, though they are referenced in part below.

<sup>14</sup> United States Patent and Trademark Office, *General Information Concerning Patents*, <http://www.uspto.gov/web/offices/pac/doc/general/index.html> (last visited June 4, 2003) [hereinafter General Information].

<sup>15</sup> United States Patent and Trademark Office, *U.S. Patent Statistics, Calendar Years 1963-2001*, [http://www.uspto.gov/web/offices/ac/ido/ocip/taf/us\\_stat.pdf](http://www.uspto.gov/web/offices/ac/ido/ocip/taf/us_stat.pdf) (last visited June 4, 2003) [hereinafter Patent Statistics]. The length of the application process presently averages 24 months. See United States Patent and Trademark Office, *Performance and Accountability Report for Fiscal year 2002*, <http://www.uspto.gov/web/offices/com/annual/2002/1-58.pdf> (last visited June 4, 2003) [hereinafter Performance and Accountability Report]. Because of this lengthy application process, these numbers are not directly comparable. In 1999, when many of the 2001-issued patents were likely applied for, 288,811 applications were received. See Patent Statistics, *supra* note 15. The USPTO states that approximately two of three patent applications result in an issued patent. See General Information, *supra* note 14. This proportion significantly overstates the rejection rate due to the unique role of continuations and continuations-in-part in the U.S. patent system. See generally Cecil D. Quillen & Ogden H. Webster, *Continuing Patent Applications and Performance of the U.S. Patent and Trademark Office*, 11 FED. CIR. B.J. 1, 9-13 (2001) (concluding that the true “grant rate” is roughly 85 percent and the true “allowance rate” is 92 percent).

<sup>16</sup> See Performance and Accountability Report, *supra* note 15, at 9.

<sup>17</sup> See General Information, *supra* note 14.

includes a variety of administrative materials and a substantive portion that usually includes the patent's proposed title, cross-referenced patents and patent applications, other relevant references, the invention's background, a summary of the invention, the specification, the claims of the patent, and drawings when appropriate.<sup>18</sup> The application's purpose is to provide the examiner, and later the public, with a clear delineation of the claimed invention.<sup>19</sup>

Nearly all proceedings before the USPTO are *ex parte*.<sup>20</sup> Therefore, except in limited circumstances, there is no advocate for those parties who assert that a patent is invalid. Indeed, for the first eighteen months, the application is itself secret.<sup>21</sup> During examination of an application, the applicant must disclose known relevant prior art, and the examiner does research for additional prior art.<sup>22</sup> Although the applicant and examiner are allowed to present arguments to one another, the adversarial system with which most litigants are familiar is almost entirely absent.

Once the application is received, it is assigned to a patent examiner.<sup>23</sup> The examiners are divided into a variety of specialties and subspecialties.<sup>24</sup> While the precise qualifications vary by field, in general, patent examiners are required to have an undergraduate degree in a relevant field.<sup>25</sup> Additional ongoing training is provided as well.<sup>26</sup> The turnover in the ranks of patent examiners is an ongoing concern for the USPTO.<sup>27</sup> In recent years, it has been viewed as a victory for attrition to be down to seven percent annually.<sup>28</sup>

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<sup>18</sup> See *id.*

<sup>19</sup> See *id.*

<sup>20</sup> See *Aptix Corp. v. Quickturn Design Sys., Inc.*, 269 F.3d 1369, 1379 (Fed. Cir. 2001) (Mayer, C.J., dissenting in part).

<sup>21</sup> See 35 U.S.C. § 122(b) (2000). Applications filed only in the United States and submitted prior to November 29, 2000, are permanently secret. See *id.*

<sup>22</sup> See General Information, *supra* note 14.

<sup>23</sup> See *id.*

<sup>24</sup> See *id.*

<sup>25</sup> United States Patent and Trademark Office, *Patent Examiner Recruitment, Qualifications*, <http://www.uspto.gov/web/offices/ac/ahrpa/ohr/jobs/qualifications.htm> (last visited Feb. 22, 2004).

<sup>26</sup> United States Patent and Trademark Office, *Patent Examiner Recruitment, Training*, <http://www.uspto.gov/web/offices/ac/ahrpa/ohr/jobs/training.htm> (last visited Feb. 22, 2004).

<sup>27</sup> Cf. Performance and Accountability Report, *supra* note 15, at 22 (describing improvements in attrition numbers).

<sup>28</sup> See *id.*

The initial review of the application results in the first office action.<sup>29</sup> The time between submission and the first office action is carefully tracked by the USPTO as part of its efforts to improve its efficiency.<sup>30</sup> At last report, this time period averages 16.7 months.<sup>31</sup> The first office action can be a grant of the patent or a rejection based on any of the conditions for patentability.<sup>32</sup> If the patent is rejected, the applicant will have an opportunity to respond by either amending claims or making arguments as to why the examiner's position is incorrect.<sup>33</sup> Even if the claim language is not amended, the statements made in this process, called the prosecution history, can limit how the patent is eventually construed.<sup>34</sup> In a complex patent application, the prosecution history may consist of several boxes, while in a more straightforward application, it may consist of just a folder.

After the response to the first office action, the patent examiner responds with either approval of the patent application or further rejections.<sup>35</sup> These rejections are often called "final rejections," reflecting the fact that the applicant does not have an absolute right to respond.<sup>36</sup> In practice, the applicant will usually be given an opportunity to respond and make further arguments or amendments.<sup>37</sup> This back-and-forth communication between examiner and applicant can continue over months or even years until either the applicant abandons the application or it is granted.<sup>38</sup> The average duration from application to issuance or abandonment is approximately two to three years, but the actual time spent by either the applicant, counsel, or examiner is nowhere near that lengthy.<sup>39</sup> A conservative estimate of the total average time spent in the active prosecution of a patent is between fifty to one hundred hours of work by the prosecuting attorney, and around twenty hours by the

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<sup>29</sup> See General Information, *supra* note 14.

<sup>30</sup> See Performance and Accountability Report, *supra* note 15, at 15.

<sup>31</sup> See *id.*

<sup>32</sup> See General Information, *supra* note 14.

<sup>33</sup> See *id.*

<sup>34</sup> See, e.g., *Festo Corp. v. Shoketsu Kinzoku Kyogo Kabushiki*, 535 U.S. 722, 727 (2002).

<sup>35</sup> See 37 C.F.R. § 1.111 - 1.114 (2000); General Information, *supra* note 14.

<sup>36</sup> See 37 C.F.R. § 1.113; General Information, *supra* note 14.

<sup>37</sup> See General Information, *supra* note 14.

<sup>38</sup> See *id.*

<sup>39</sup> See Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1500 (2001) [hereinafter Lemley, *Rational Ignorance*].

patent examiner.<sup>40</sup>

While many examiners are experienced and highly competent, criticism of the patent application process is widespread.<sup>41</sup> Commentators argue that examiners have insufficient expertise to accurately determine if an application represents an advance over the prior art.<sup>42</sup> As noted, a patent examiner is required only to have an undergraduate degree in a relevant field,<sup>43</sup> whereas many patent applications realistically require more specialized knowledge.<sup>44</sup>

A second criticism of the USPTO is that patents are inappropriately issued, resulting in virtually any application's acceptance provided the inventor is sufficiently persistent.<sup>45</sup> Indeed, the USPTO's mission is to grant patents.<sup>46</sup> A prime criticism in recent years has been focused on "business methods" patents, embodied by the Amazon.com patent on "one-click" shopping.<sup>47</sup> Some commentators criticize the conceptual basis for patenting business methods, while others simply believe that a substantial number of those patents are invalid and should never have been granted.<sup>48</sup>

Perhaps the strongest criticism targets jury verdicts invalidating patents. According to one study of infringement cases decided in 2001, around fifty to sixty jury verdicts included the invalidation of a patent, or a finding that a patent was unenforceable.<sup>49</sup> Similar studies have found that half of patents litigated are found invalid by juries.<sup>50</sup> Presumably a

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<sup>40</sup> See *id.* at 1499-1500.

<sup>41</sup> See, e.g., Lemley, *Rational Ignorance*, *supra* note 39 (arguing that improving the Patent Office examination process is not cost-effective, preferring a more searching inquiry into patents' validity by the courts); see also James Gleick, *Patently Absurd*, N.Y. TIMES MAG., Mar. 12, 2000, at 44.

<sup>42</sup> See, e.g., Lemley, *Rational Ignorance*, *supra* note 39, at 1495-96 n.2 (noting the USPTO's failure to "hire examiners skilled in the software arts or to allow software engineers to practice before it, and failing to classify software prior art well").

<sup>43</sup> See *supra* note 25 and accompanying text.

<sup>44</sup> See Lemley, *Rational Ignorance*, *supra* note 39, at 1495-96 n.2.

<sup>45</sup> See *id.* at 1523-24.

<sup>46</sup> See *id.*

<sup>47</sup> U.S. Patent No. 5,960,411, <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=/netahtml/srchnum.htm&r=1&f=G&l=50&s1=5,960,411.WKU.&OS=PN/5,960,411&RS=PN/5,960,411> (last visited February 13, 2004); see also generally Gleick, *supra* note 41.

<sup>48</sup> See Gleick, *supra* note 41.

<sup>49</sup> See University of Houston Law Center, *Decisions for 2001*, <http://www.patstats.org/2001.html> (last visited Aug. 11, 2003).

<sup>50</sup> See John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity*

significant number of infringement claims are never asserted, or if asserted, relatively small settlements are reached.<sup>51</sup>

Notwithstanding the criticism, some consider the United States' patent system a key factor in U.S. innovation, outweighing its possible deficiencies.<sup>52</sup> If successful, the applicant receives a patent representing the government's conclusion that the invention described in the application is both worthy of protection and of a temporary monopoly. To put it in the context of the Phelox hypothetical, based on a half-week of consideration by the examiner, MegaPharma will get a lengthy monopoly on its product, and, as discussed *infra*,<sup>53</sup> a presumption in any subsequent litigation that the monopoly is appropriate.

## B. FDA APPROVAL

The process of putting a drug through the development and approval process is a lengthy and expensive one. Recent studies indicate that the average cost of developing a drug is roughly \$800 million.<sup>54</sup> Seventeen new drugs were approved by the FDA in 2002, and the average period from application to approval was 17.8 months.<sup>55</sup> To handle the INDs and NDAs it receives each year, the FDA employs hundreds of reviewers in various fields.<sup>56</sup> The Center for Drug Evaluation and Research ("CDER") describes its job as "ensuring that drugs are safe and

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*of Litigated Patents*, 26 AIPLA Q.J. 185, 206-7 (1998).

<sup>51</sup> The USPTO itself has concluded that, between 1999 and 2002, from 4.2% to 6.6% of issued patents have at least one claim that would be held invalid if considered by a court. See Performance and Accountability Report, *supra* note 15, at 18.

<sup>52</sup> See Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 993-1000 (1997) (describing the commonly assumed idea that the patent system encourages innovation); cf. Mark A. Lemley, *Reconceiving Patents in the Age of Venture Capital*, 4 J. SMALL & EMERGING BUS. L. 137 (2000) (noting studies challenging the innovation story while giving the notion due accord).

<sup>53</sup> See *infra* section II.

<sup>54</sup> See PhRMA, *Most Drugs Never Recoup the Average Cost of Development*, <http://www.phrma.org/publications/quickfacts/16.04.2003.717.cfm> (Mar. 26, 2003) [hereinafter PhRMA]. PhRMA is an industry advocacy group that may be interested in emphasizing the high costs of drug development.

<sup>55</sup> See PhRMA, *New Drug Approvals in 2002*, 1, <http://www.phrma.org/newmedicines/resources/2003-01-30.102.pdf> (last visited August 11, 2003) [hereinafter PhRMA, *New Drug Approvals in 2002*].

<sup>56</sup> "[The] CDER is the largest of the FDA's five centers, with a staff of about 1,800." Tamara Nordenberg, *Inside FDA: The Center for Drug Evaluation and Research*, FDA CONSUMER MAG., July-Aug. 1996, <http://www.fda.gov/fdac/features/696cdcr.html> (last visited Aug. 11, 2003).

effective.”<sup>57</sup>

Some sources list the average time from discovery through approval as ten to fifteen years.<sup>58</sup> The process of discovery through filing an IND could take an average of six to seven years, followed by another six to seven years of clinical trials, with a further eighteen months prior to approval by the FDA.<sup>59</sup> Given five thousand compounds that reach preclinical studies, only five are tested in humans, and of those five, one eventually obtains approval by the FDA.<sup>60</sup>

NDAAs are themselves extraordinary documents. An NDA typically runs over 100,000 pages.<sup>61</sup> It contains all data from the sponsor’s study of the drug in preclinical and clinical trials, along with the sponsor’s interpretation of these data.<sup>62</sup> It represents the results of thousands of hours of work and millions of dollars.<sup>63</sup>

The FDA review process includes reviewers from a number of disciplines working in tandem. Statisticians, chemists, pharmacologists, physicians, pharmacokineticists, and, when appropriate, microbiologists, are all involved in reviewing the data provided by the drug’s sponsor.<sup>64</sup>

The NDA process is essentially *ex parte*, although there can be more public information available concerning the application status than can be found in the patent context.<sup>65</sup> Requests for additional testing, rejections, grants, and review panels<sup>66</sup> are all public activities, and an NDA filing is frequently announced by the sponsor in press releases.<sup>67</sup> While the application process occasionally enters the public domain, it

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<sup>57</sup> See *id.*

<sup>58</sup> See PhRMA, *New Drug Approvals in 2002*, *supra* note 55, at 17.

<sup>59</sup> See *id.*

<sup>60</sup> See *id.*

<sup>61</sup> See *id.*

<sup>62</sup> See *id.*

<sup>63</sup> See *id.*

<sup>64</sup> See FDA, *Benefit vs. Risk: How CDER Approves New Drugs*, <http://www.fda.gov/cder/about/whatwedo/testtube-5.pdf> (last visited Aug. 11, 2003) [hereinafter FDA, *Benefits vs. Risk*].

<sup>65</sup> See, e.g., Press Release, AstraZeneca, *AstraZeneca Submits its New Superstatin, CRESTOR™, for Regulatory Approval in the US and Europe. Development of VIOZAN™ COPD Treatment to be Discontinued; Resources to be Re-allocated to More Promising Products in R&D Pipeline*, <http://www.astrazeneca.com/pressrelease/393.aspx> (June 27, 2001); see also Lemley, *Rational Ignorance*, *supra* note 39, at 1499.

<sup>66</sup> See *infra* notes 74-80 and accompanying text.

<sup>67</sup> See, e.g., Press Release, AstraZeneca, *supra* note 65.

remains fundamentally non-adversarial.<sup>68</sup> The data are reviewed and reviewers provide recommendations as to whether the product should be approved.<sup>69</sup> Based on these recommendations and further study of the underlying data, the FDA chooses to approve the drug, reject the application, or request additional information.<sup>70</sup>

The review process, while subject to criticism<sup>71</sup>, is not generally considered a rubber stamp. Recent high-profile rejections<sup>72</sup> and demands for additional data<sup>73</sup> demonstrate that the FDA will not approve all applications. The FDA also regularly appoints a review panel, made up of neutral third-party physicians, scientists, and others to examine the data from a specialist's point of view.<sup>74</sup>

This process is time and labor intensive. Recall that the time from NDA submission to approval averages about twenty months.<sup>75</sup> These twenty months are not spent waiting for responses, but rather spent analyzing and reviewing the submitted NDA, and participating in discussions between the FDA and the sponsor.<sup>76</sup> The time from the IND to the NDA averages seven years, and the time from discovery to the IND averages six and a half years.<sup>77</sup>

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<sup>68</sup> See FDA, *Benefits vs. Risk*, *supra* note 64.

<sup>69</sup> See *id.*

<sup>70</sup> See *id.*

<sup>71</sup> See *supra* notes 41-45 and accompanying text.

<sup>72</sup> The Imclone cancer drug Erbitux's rejection by the FDA in 2001 was subject to great press interest. The Erbitux application was recently resubmitted to the FDA. See Matthew Herper, *Puncturing the ImClone Hype*, [http://www.forbes.com/technology/2003/06/02/cx\\_mh\\_0602imclone.html](http://www.forbes.com/technology/2003/06/02/cx_mh_0602imclone.html) (June 6, 2003).

<sup>73</sup> Crestor, a member of the class of anti-cholesterol medications known as statins, was ultimately approved with a lower dosage range than proposed by its sponsor AstraZeneca. See FDA Advisory Committee Meeting Briefing Document NDA 21-366 for the use of CRESTOR, [http://www.fda.gov/ohrms/dockets/ac/03/briefing/3968B1\\_02\\_A-FDA-Clinical%20Review.pdf](http://www.fda.gov/ohrms/dockets/ac/03/briefing/3968B1_02_A-FDA-Clinical%20Review.pdf) (June 11, 2003); FDA Talk Paper, U.S. Food and Drug Administration, FDA Approves New Drug for Lowering Cholesterol, T03-61, <http://www.fda.gov/bbs/topics/ANSWERS/2003/ANS01247.html> (Aug. 12, 2003).

<sup>74</sup> Indeed, the approval of Crestor occurred only after such a meeting. See FDA Advisory Committee Meeting, *supra* note 73.

<sup>75</sup> See *supra* note 59 and accompanying text.

<sup>76</sup> See Lemley, *Rational Ignorance*, *supra* note 39, at 1500.

<sup>77</sup> See John T. Kelly, *The Drug Development and Approval Process*, New Drug Approvals in 2002, 17, <http://www.phrma.org/newmedicines/resources/2003-01-30.102.pdf>; see also PhRMA, *New Drug Approvals in 2002*, *supra* note 55, at 17.

An important part of the evaluation by the FDA is the determination of what information goes into a drug's package insert.<sup>78</sup> FDA approval of a drug does not allow the manufacturer to market it however it sees fit or for any use it wishes to pitch. Instead, the approval carries with it an important phrase: "adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text."<sup>79</sup> Marketing outside the label results in the drug being misbranded.<sup>80</sup> However, with respect to use and marketing within the label, the approval denotes that the drug is safe and effective.<sup>81</sup>

Unlike the patent process,<sup>82</sup> the FDA involvement in a drug does not end with its approval.<sup>83</sup> The FDA has a perpetual, extensive monitoring process and ongoing authority over the drug sponsors to require additional information, testing, or actions, from label changes up to and including involuntary product withdrawal or recall.<sup>84</sup> Every time the drug company wishes to change the package insert in order to add an indication, a warning, or a dose, the FDA must decide once again whether the product is indeed safe and effective by considering the data from the clinical trials as well as information from post-marketing reports.<sup>85</sup>

After a drug company begins marketing a drug, it remains responsible for reporting to the FDA any adverse events it learns of on a specific schedule.<sup>86</sup> Reporting to either the FDA

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<sup>78</sup> See Letter from Center for Drug Evaluation and Research to Parke-Davis Pharmaceutical Research, <http://www.fda.gov/cder/foi/appletter/1998/20702ltrs003s005.pdf> (Jul. 10, 1998) (FDA letter approving Lipitor).

<sup>79</sup> *Id.*

<sup>80</sup> See 21 U.S.C. § 321(n) (2000); *Henley v. FDA*, 77 F.3d 616, 621 (2d Cir. 1996).

<sup>81</sup> See, e.g., Letter from David G. Orloff, Director, Division of Metabolic and Endocrine Drug Products, Center for Drug Evaluation and Research, to Christopher Graham, Director, Worldwide Regulatory Strategy, Pfizer, Inc., <http://www.fda.gov/cder/foi/appletter/2002/20702se5-033ltr.pdf> (Oct. 18, 2002) (2002 FDA letter approving a label change for Lipitor, including "safe and effective" finding).

<sup>82</sup> In very rare circumstances, the USPTO will reconsider previously issued patents. See Performance and Accountability Report, *supra* note 15, at 106 (noting that in 2002, 272 requests for reexamination were received, of which 200 were granted).

<sup>83</sup> See Nordenberg, *supra* note 56.

<sup>84</sup> See *id.*

<sup>85</sup> See *id.*

<sup>86</sup> See *id.*



or the drug company by healthcare providers or others is entirely voluntary.<sup>87</sup> These adverse event reports are not considered to be a reliable basis for determining causation or incidence rate.<sup>88</sup> However, they can be valuable in generating hypotheses or signals of potential safety issues, and drug companies and the FDA monitor them closely.<sup>89</sup> The FDA also occasionally performs audits of pharmaceutical companies' drug safety departments, evaluating whether the processes are in place for appropriate handling of the event reports and whether those processes are followed correctly.<sup>90</sup>

Like the USPTO, critics argue that the FDA's review and ongoing monitoring process is inadequate.<sup>91</sup> The approval process is based almost entirely on self-reporting by the pharmaceutical companies.<sup>92</sup> These companies have an apparent interest other than full disclosure.<sup>93</sup> The FDA does not perform its own trials, and clinical trials are performed by physicians who are paid by the pharmaceutical companies themselves.<sup>94</sup> Critics also charge that the FDA is more focused on reducing approval times than on ensuring that approval is appropriate, and further assert that the agency has been captured by the companies it regulates.<sup>95</sup> Based on these and other criticisms, these critics argue that the pharmaceutical companies can get a defective drug approved by concealing unfavorable data, intentionally forging experiments to uncover data that would

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<sup>87</sup> See Center for Drug Evaluation and Research, *Advanced Event Reporting System*, <http://www.fda.gov/cder/aers/default.htm> (last visited Feb. 22, 2004) (describing the AERS voluntary reporting system) [hereinafter AERS Description].

<sup>88</sup> 21 C.F.R. § 314.80(k) (2003).

<sup>89</sup> See AERS Description, *supra* note 87.

<sup>90</sup> See, e.g., Presentation by Nancy Haggard, Post-Marketing Adverse Drug Experience Manager, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, <http://www.fda.gov/cder/present/dia-62000/haggard/haggard.ppt> (Jun. 13, 2000).

<sup>91</sup> See, e.g., Lars Noah, *Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability*, 88 GEO. L.J. 2147 (2000).

<sup>92</sup> See, e.g., *id.* at 2154-55.

<sup>93</sup> Pharmaceutical companies disagree, noting the long-term harm caused by problems with products and the serious risks in litigation of hiding information from the FDA. See, e.g., PhRMA, *Monitoring the Safety of Drugs*, <http://srpub.phrma.org/papers/12.16.98.drug.safety.html> (last visited Aug. 11, 2003).

<sup>94</sup> See, e.g., Lexchin et al., *Pharmaceutical Industry Sponsorship and Research Outcome and Quality: Systematic Review*, 326 BRIT. MED. J. 1167, 1170 (2003) (concluding that the sponsors of studies do affect the outcomes).

<sup>95</sup> See, e.g., Noah, *supra* note 91, at 2154 (rejecting arguments that the FDA has been captured by the industries it regulates).

render the drug not approvable, and using connections or lobbying power to ensure approval.<sup>96</sup> Even with the number of employees at the FDA involved in evaluating a new drug, the sheer volume of material submitted makes them, according to critics, incapable of doing a genuinely in-depth analysis.<sup>97</sup>

Similar charges are leveled at the ongoing monitoring of pharmaceuticals and adverse events. The section of employees tracking the relevant data is sometimes characterized as under-funded and under-qualified.<sup>98</sup> As with the approval process, critics note that adverse event data comes largely from the companies being regulated, and thus critics suggest that these data can be affected improperly by these companies.<sup>99</sup>

Juries provide some implicit criticism as well. Huge damage rewards in pharmaceutical tort litigation indicate that at least some juries have concluded that certain FDA-approved products are not safe and effective.<sup>100</sup> Still, it is unlikely that even the most ardent critic of the FDA would contend that the FDA's approvals are wrong one in twenty times, while the USPTO itself identifies that proportion as the *goal* for errors in patent grants.<sup>101</sup> As in the patent context, most observers tend to agree that the U.S. system of drug approval is among the best in the world.<sup>102</sup> The FDA gets life-saving or life-improving drugs onto the market in a reasonable time frame while preventing most drugs with a negative risk-benefit ratio from reaching the market.<sup>103</sup>

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<sup>96</sup> See, e.g., Robert L. Rabin, *Reassessing Regulatory Compliance*, 88 GEO L. J. 2049, 2076 (2000) (rejecting a regulatory compliance defense, citing flaws in the regulatory system).

<sup>97</sup> See, e.g., Arnst et al., *New Drugs: Why So Many Delays?*, BUSINESSWEEK, Mar. 11, 2002, at 62-63 (citing varied approval standards and accelerated approval of new drugs based on overeager pharmaceutical companies and an under-funded FDA).

<sup>98</sup> See, e.g., *The Food and Drug Law Institute's 45th Annual Educational Conference Keynote Addresses*, 57 FOOD DRUG L. J. 227, 229-30 (2002).

<sup>99</sup> See, e.g., Noah, *supra* note 91, at 2154.

<sup>100</sup> See, e.g., *AHP Settles Recent Verdict*, 5 MEALEY'S LITIGATION REPORT: FEN-PHEN/REDUX Iss. 1, 4 (Nov. 2001) (reporting a \$9 million settlement in a case in which the jury had awarded \$56.5 million).

<sup>101</sup> See Performance and Accountability Report, *supra* note 15, at 13.

<sup>102</sup> See, e.g., Symposium, *Economic Models of the Emerging Biotechnology Industry*, 27 SUFFOLK U. L. REV. 1525, 1546 (1993).

<sup>103</sup> One might question whether approving another in a long series of SSRIs (as in the hypothetical) is a useful activity for the FDA. Without going into detail, there is broad agreement that having more safe and effective drugs in a particular class is valuable, due generally to individuals' idiosyncratic responses to medications and to the effects of competition on drug pricing. See

## C. PATENT ISSUANCE AND FDA APPROVAL COMPARED

In certain ways, the patent application and drug approval processes are similar. Each can take a number of months, each involves evaluation by people who are at least theoretically trained for the job they perform, and each results in a license from the government for certain conduct. On the other hand, the extent of the review is quite different. The patent application process generally represents a couple hundred of hours of work, including an average of only twenty hours by the examiner. In contrast, the NDA process, if it reaches completion, represents thousands or tens of thousands of hours of work and testing on thousands of patients.<sup>104</sup> The USPTO review generally is performed by one person, or two if a supervisor is involved.<sup>105</sup> The FDA review involves a significantly larger number of people from an array of specialties. Significantly, the FDA involvement continues throughout the marketing of a drug as well, so that the approval is not a one-time event.<sup>106</sup> It is certainly fair to say that the NDA process is a much “bigger” process than the patent process.

Part II of this article compares the respective systems in more detail. For now, it is enough to conclude that the FDA review is *at least* as exhaustive as the USPTO's. With that in mind, this article next analyzes how the USPTO and FDA reviews play out in litigation.

## II. THE EFFECTS OF PATENT ISSUANCE OR FDA APPROVAL ON LITIGATION

## A. PATENT ISSUANCE-PRESUMPTION OF VALIDITY

Despite the criticisms of the patent process outlined above, patents are protected by a statutory presumption of validity.<sup>107</sup> In recognition that the USPTO, as an agency, is considered the expert on patentability; juries are not permitted to find that a patent is invalid merely by a preponderance of the evidence. Instead, the finding must be by clear and convincing evi-

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In re Rezulin Prod. Liab. Litig., 168 F. Supp. 2d 136, 146 (S.D.N.Y. 2001) (noting that individual patients are affected differently by the same medication).

<sup>104</sup> See *supra* Part I.B.

<sup>105</sup> See *supra* Part I.A.

<sup>106</sup> See *supra* Part I.B.

<sup>107</sup> 35 U.S.C. § 282.

dence.<sup>108</sup> Further, juries are usually specifically instructed by the judge that a patent is to be presumed valid.<sup>109</sup>

Information about the value of the patent office's review comes not only from the patent-holder's attorney, but also from the judge. The psychological impact of this presumption of validity is difficult to measure. However, it is not insignificant that a jury is instructed by the one nominally neutral person in the courtroom that it *must* begin deliberations with the belief that the patent is valid.<sup>110</sup>

These presumptions are codified in the Patent Act of 1952.<sup>111</sup> Congress, implementing the Constitution's mandate, had set up an agency specifically tasked to evaluate patent applications and give inventors a lengthy monopoly on their inventions. Because that agency was *the* specialist in determining the patentability of a particular invention, the presumption of validity was created, first judicially and then later codified by Congress.<sup>112</sup>

While it is difficult to evaluate the effect of the presumption of validity numerically, there is little doubt in the patent litigation bar that it is significant. Litigants emphasize it in openings, in closings, and everywhere else possible. Jury research indicates that it makes a difference.<sup>113</sup> The only person

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<sup>108</sup> *Id.*

<sup>109</sup> At a minimum, the jury is told that the burden of proof on invalidity must be met by clear and convincing evidence. *See* Model Patent Jury Instructions for the N.D.Cal., n.1 (Jan. 18, 2002). There is some debate on whether the instructions should expressly include a statement that the USPTO's determination is to be presumed correct. *See id.* Regardless of whether that statement is included, every jury is told that invalidity must be found by a high evidentiary standard such as clear and convincing evidence. *See id.* (discussing how the burden demonstrates the clear and convincing standard); *see also id.* at 22 (indicating that the jury should find a patent invalid only if highly probable).

<sup>110</sup> This instruction is likely better respected than the presumption of innocence. Most jurors presumably have relatively little experience with the patent system, and thus have no reason to believe it grants patents without a good basis. Yet, ample data suggests that jurors believe the fact that someone is charged with a crime suggests that the person likely did something wrong, notwithstanding constitutional presumptions. *See The View from the Jury Box: Many Jurors Consider Deep Pockets and Ignore Presumption of Innocence*, 15 NAT'L L.J. S12 (1993).

<sup>111</sup> H.R. REP. NO. 1923, at 2523 (1952).

<sup>112</sup> 35 U.S.C. § 282; *see generally* Editorial Notes, 21 GEO. WASH. L. REV. 575 (1953).

<sup>113</sup> *See* Nicholas M. Cannella & Timothy J. Kelly, *Jury Trials and Mock Jury Trials*, 1 PAT. LITIG. 731, 739 (1993) (PLI Patents, Copyrights, Trademarks, and Literary Property Handbook Series No. G-375) (summarizing jury research indicating a belief in extensive USPTO review and deference to that

in the courtroom who the jury might see as having no agenda is the judge, and he or she is telling the jury to presume that the patent is valid.<sup>114</sup> Like the patent process itself, the presumptions given patent holders are the subject of extensive criticism.<sup>115</sup> Once that criticism is examined more carefully, however, it generally becomes clear that concerns about the patent office rather than the presumption of validity is the basis for the criticism.<sup>116</sup> With some notable exceptions,<sup>117</sup> most critics are not calling for an end to the presumption of validity and its accompanying procedural advantages, and no critics seem to argue that the presumption has no effect. Rather, the critics argue that the patenting process should be improved.

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review).

<sup>114</sup> See Kimberly A. Moore, *Judges, Juries, and Patent Cases—An Empirical Peek Inside the Black Box*, 99 MICH. L. REV. 365, 408-09 (2000) (concluding that juries find for the patent-holder more often than judges).

<sup>115</sup> See Jay Kesan, *Carrots and Sticks to Create a Better Patent System*, 17 BERKELEY TECH. L.J. 763, 763-64 (2002); Lemley, *Rational Ignorance*, *supra* note 39; FTC, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, 8 <http://www.ftc.gov/os/2003/10/innovationrptsummary.pdf> (last visited December 15, 2003).

<sup>116</sup> Kesan, *supra* note 115, at 765-66.

<sup>117</sup> Jay Kesan has proposed the following as one strategy to deal with the presumed problems in the USPTO: the elimination of the presumption of validity if the patentee does not disclose more than the current minimal prior art, and in which the presumption of validity only exists with respect to disclosed prior art. See Kesan, *supra* note 115. Mark Lemley argues that limiting the presumption of validity to prior art references and arguments actually considered by the examiner would have the adverse effect of flooding the examiner with prior art. Lemley, *Rational Ignorance*, *supra* note 39, at 1528-1529. His ultimate proposal, based on a conclusion that a very small proportion of issued patents are actually asserted or litigated, is that the presumption of validity should exist, but only require proof by a preponderance of the evidence to overcome. *Id.* In other words, we should accept the fact that we have a good, but not great, patent office, and treat its conclusions accordingly. Lemley, *Rational Ignorance*, *supra* note 39, at 1528-1529.

Recently the Federal Trade Commission urged the abandonment of the presumption of validity standard for many of the reasons cited in this article. See FTC, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, *supra* note 115, at 8-20 (proposing a reduction in the burden of proof to a preponderance of the evidence).

This article operates from the assumption that the presumption of validity makes some sense in the patent context, but the idea of eliminating the presumption entirely because the examination is so minimal adds support to my view that the FDA review is relatively superior to the USPTO review. Without giving the subject full review, resources would generally be better allocated if the presumption of validity were modified or removed rather than spending more money on the USPTO.

## B. FDA APPROVAL-NO PRESUMPTION OF SAFETY

In typical pharmaceutical litigation, a substantial portion of the plaintiffs' effort is directed at undermining the FDA's determination of safety and efficacy. In most mass tort litigation, defendants are accused of failing to disclose required information to the FDA, specifically data from clinical trials, adverse event reports, preclinical data, or any other material information.<sup>118</sup> On the other hand, to build on any evidence of non-compliance, plaintiffs spend considerable resources on efforts to diminish the resources or skills of the FDA. For example, through an "FDA expert," juries will hear about the FDA being overwhelmed with data, understaffed, or simply filled with incompetent bureaucrats.<sup>119</sup>

This road goes both ways. Defendants get all the mileage they can from FDA approval, regardless of the actual extensiveness of the review and monitoring involved. If the facts support it, defendants emphasize the complete and voluminous information provided to the FDA. They may even bring an entire NDA, possibly hundreds of boxes, into the courtroom. They establish the absence of FDA sanction for any regulatory violations, and discuss at length the approval and ongoing monitoring process discussed above.<sup>120</sup> If they have "clean" reports from FDA audits or inspections, those reports will surely be blown up on large demonstrative exhibits.

From the defense's perspective, juries will hear about the FDA as a model government agency second to none. Its employees are impeccably thorough, highly trained, unrivaled in

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<sup>118</sup> For example, the public interest group Public Citizen requested that criminal charges be brought against Abbott Laboratories for allegedly failing to comply with reporting requirements regarding eight deaths and other adverse events among patients taking the diet drug Meridia. Sidney M. Wolfe, *Letter to Dept. of Health and Human Services*, <http://www.citizen.org/publications/release.cfm?ID=7175>. These allegations almost immediately made their way into plaintiffs' attorneys' advertising for clients. See, e.g., Belluck & Fox, LLP, *All About Meridia's Dangers*, at <http://www.meridiarecall.com/news.htm>. These allegations can be analogized to claims of inequitable conduct in patent applications where patentees are alleged to have withheld material prior art or other information from the Patent Office. Michael Green has suggested that having a compliance defense based on compliance with regulatory requirements would shift the focus of litigation to proving noncompliance rather than reducing the litigation overall. See Michael D. Green, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. MICH. J.L. REFORM 461, 507-09 (1997).

<sup>119</sup> See, e.g., *Medrano v. Am. Home Prod. Corp.*, No. B-150-760-B (Tex. Dist. Ct. Apr. 9, 1999) (cited in 2 No. 9 Andrews Diet Drugs Litig. Rep. 14).

<sup>120</sup> See *supra* Part I.B.

their dedication to patient safety, and never hesitant to act when needed, despite any commercial consequences. The approval process is the model for the world and is nearly perfect, as the argument goes.

The current tort system is the subject of extensive criticism, largely from those who believe it exposes defendants to too much liability based on bad science. This criticism ranges from editorials in the popular press warning of dire consequences<sup>121</sup> to the academic press.<sup>122</sup> The first line of criticisms generally focuses on prominent verdicts based on purportedly unfounded expert testimony that ultimately convinces a jury that causation exists where the weight of scientific evidence says it does not. Often, the critics argue that the threat of large and unjustifiable verdicts against pharmaceutical companies risks dampening the quest for new drugs to treat serious diseases or conditions.

Certain states have implemented an "FDA defense" that allows pharmaceutical defendants to receive either presumptions in their favor or general immunity from punitive damages with certain exceptions.<sup>123</sup> Texas's implementation of the "FDA defense", which is the closest to this article's proposal, has only been in effect for a few months.<sup>124</sup> The application and results of the defense should be interesting, given the enormous amount of litigation surrounding the pharmaceutical industry centered in Texas.

If Texas's statute withstands the inevitable constitutional challenges, FDA-approved drugs will receive, in the context of failure-to-warn cases, a rebuttable presumption that the labeling is appropriate. The presumption can be overcome by showing that the defendant (a) made material misrepresentations to the FDA, (b) continued to sell the drug after being ordered to withdraw it by the FDA, (c) recommended off-label use, or (d)

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<sup>121</sup> See, e.g., Shad Rowe, *Texas Tort Reform Can Be a Model for Other States*, HOUSTON BUS. J. (July 11, 2003), <http://www.bizjournals.com/houston/stories/2003/07/14/editorial4.html>.

<sup>122</sup> See, e.g., Michael D. Green, *Safety as an Element of Pharmaceutical Quality: The Respective Roles of Regulation and Tort Law*, 42 ST. LOUIS U. L.J. 163, 165 (1998).

<sup>123</sup> See MICH. COMP. LAWS § 600.2946(5) (precluding suit if the drug in question is FDA approved and the manufacturer complied with relevant regulations); TEX. CIV. PRAC. & REM. CODE §§ 82.007 & 82.008(a) (2004).

<sup>124</sup> TEX. CIV. PRAC. & REM. CODE §§ 82.007 & 82.008(a) (2004); see Rowe, *supra* note 124.

prescribed an off-label use.<sup>125</sup>

### III. AN ANALYSIS OF DEFERENCE

One reaction to the situations described above is the conclusion that all agency decisions should be treated the same in litigation. After all, each agency, whether it is the FDA, the USPTO, or some other agency, is presumably an expert in its field and should be accorded some deference as a result. Nevertheless, the level of review and the interests being protected vary dramatically among various agencies.<sup>126</sup> Furthermore, in litigation implicating agency determinations, the interests of the courts will vary dramatically. This part of the article addresses some of those interests, and suggests what factors should be considered when considering the agencies in question.

#### A. GOVERNMENTAL INTERESTS IN EACH AGENCY

Through its myriad agencies, the federal government makes thousands of decisions daily, from approvals of political marches in national parks to the issuance of patents. Most of those decisions could ultimately end up being challenged in court, whether by parties arguing that the criteria applied were unconstitutional, or by parties disputing the factual basis of the decisions. As outlined above, how these decisions are considered in litigation varies rather dramatically, at least in the two example situations. The purpose of the agencies' determinations is thus a first question in deciding whether the present treatment of patent approvals and FDA approvals is appropriate.

##### 1. The USPTO

The USPTO was established by Congress "to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."<sup>127</sup> The primary role of the USPTO is to issue patents, but some commentators argue that

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<sup>125</sup> TEX. CIV. PRAC. & REM. CODE § 82.008(b) (2004).

<sup>126</sup> As described below, the agencies' treatments are arguably reversed: the more thorough agency gets less deference. Yet, the elements explored en route to that conclusion do indicate that different treatment can be appropriate.

<sup>127</sup> U.S. CONST. art. I, sec. 8, cl. 8.



it takes that goal too far by issuing too many of them.<sup>128</sup> An initial question, then, is whether we want the government to issue patents at all. A robust patent system is often considered critical to maintaining a steady stream of innovations resulting in economic stimulus and technological advancement.<sup>129</sup> To put it in the hypothetical's context, if MegaPharma genuinely did invent the SSRI in question but the patent system did not exist, a generic drug company would, as a result of avoiding the research and development costs incurred by MegaPharma, rapidly release a generic version of Phelox and charge less for it. Therefore, MegaPharma would lose its incentive to innovate.

On the other hand, the desire to provide incentives to innovate is not the same as a desire to issue undeserved patents. An incorrectly issued patent causes significant harm as well, since companies that would otherwise consider entering the market might stay out as a result. Furthermore, if another company thought the patent was invalid, the financial hurdle created by having to litigate the patent's validity is sizable and, especially considering the presumption of validity, carries a large element of risk.<sup>130</sup>

It is important to note that an incorrectly issued patent will not have an adverse effect on the public at large, except insofar as it will have the potential to slow innovation. In most cases, it is not likely to put citizens' health or lives in danger.<sup>131</sup> Moreover, a very small proportion of patents are actually litigated. Most sit in a binder, and a surprising number are abandoned.<sup>132</sup>

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<sup>128</sup> See *supra* notes 41-48 and accompanying text.

<sup>129</sup> But see Lemley, *Reconceiving Patents in the Age of Venture Capital*, *supra* note 52 (suggesting that in the age of venture capital, the incentive of innovation is no longer as significant a factor in innovation as it once was).

<sup>130</sup> Attorneys' fees are available only in "exceptional" cases. 35 U.S.C. § 285. Again, there have been proposals for increasing the availability of fees in the context of patents that are found to be invalid. See Kesan, *supra* note 115.

<sup>131</sup> In the pharmaceutical context, notable exceptions exist. The most publicity in recent years has focused on patent protection for drugs that treat life-threatening diseases. As of this writing, the World Trade Organization is on the verge of approving a pact to permit the elimination of patent protection on certain AIDS drugs for low-cost distribution in developing countries. See *WTO Votes To Bypass Patents on Medicines Cheap Generics Go To Poor Nations*, WASH. POST, Aug. 31, 2003, at A16. Less health-oriented but still important is the fact that an improperly granted patent may result in the public paying monopoly prices when it should not have to do so. Notwithstanding these important exceptions, this article maintains that most patent grants or denials have minimal impact on the public, whether the decisions are right or wrong.

<sup>132</sup> Lemley, *Rational Ignorance*, *supra* note 39.

When presented with a close call on whether or not to issue a patent, one might appropriately conclude that the USPTO should grant the patent. Granting patents is, after all, its mission; and the negatives of getting it wrong, while not negligible, are not devastating.<sup>133</sup> In short, the government's interest in the USPTO includes granting patents, as well as making correct decisions on patentability most of the time. The USPTO's mistakes get fixed by the courts and, for the most part, cause compensable financial harm without enormous public problems.

## 2. FDA

The FDA is, at its foundation, a public health agency. Its mission is to:

(1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;

(2) with respect to such products, protect the public health by ensuring that—

(A) foods are safe, wholesome, sanitary, and properly labeled;

(B) human and veterinary drugs are safe and effective;

(C) there is reasonable assurance of the safety and effectiveness of devices intended for human use;

(D) cosmetics are safe and properly labeled; and

(E) public health and safety are protected from electronic product radiation;

(3) participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements; and

(4) as determined to be appropriate by the Secretary, carry out paragraphs (1) through (3) in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.<sup>134</sup>

The FDA does not exist to stimulate the economy, or to en-

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<sup>133</sup> Recall the earlier discussion of the quality goals of the USPTO. See *supra* Part I.A. Mark Lemley notes that the Patent Office has had (at least at one point) a large poster by its entrance stating that its goal was to “help[] our customers get patents.” Lemley, *Rational Ignorance*, *supra* note 39, at n.3.

<sup>134</sup> FDA Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 § 406.

sure the rapid delivery of drugs to consumers. It exists to “promote” and “protect” the public health and, in the pharmaceutical context, to ensure that drugs are “safe and effective.”<sup>135</sup> The approval of a drug that is either unsafe or ineffective has the potential to cause serious injury or death. On a more mundane but still important note, it may also result in public and private funds being spent on drugs that are less safe or less effective than believed by consumers.

The fact that the role of the FDA does not include stimulating the economy does not mean that its decisions have no economic impact. Pfizer, the largest research-based pharmaceutical company, now has the third largest market capitalization in the world,<sup>136</sup> and health care expenses continue to consume a large portion of the United States gross domestic product.<sup>137</sup> New drugs can help productivity, reduce (or increase) health care costs, and extend the productive (or nonproductive) life of residents. Nonetheless, the *purpose* of the FDA is, at least nominally, to protect and promote the public health independent of the economic impact of its decisions.<sup>138</sup>

Another factor relevant to the interests in play relates to the use of the licenses. As noted earlier, a very small percentage of issued patents ever get “used.” In contrast, virtually all approved drugs are marketed. While a mistake in the patent context is very likely never to get noticed, a mistake in approving a drug almost certainly will.

If the core motivation of the FDA is indeed public health, then a close call with respect to safety should be made on the side of caution, and every question relating to safety should be examined with great care. Mistakes will happen, but they should rarely be tolerated. Review of mistakes should be examined more carefully than in other contexts. Though damage

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<sup>135</sup> *Id.*

<sup>136</sup> Pfizer.com., *Pfizer and Pharmacia Combine Operations, Create World's Largest Research-Based Pharmaceutical Company*, [http://www.pfizer.com/are/investors\\_releases/mn\\_2003\\_0416.cfm](http://www.pfizer.com/are/investors_releases/mn_2003_0416.cfm) (Apr. 16, 2003).

<sup>137</sup> Center for Medicare & Medicaid Services, *Program Information: On Medicare, Medicaid, SCHIP & Other Programs of the Centers for Medicare & Medicaid Services*, 3, <http://cms.hhs.gov/charts/series/sec1.pdf> (Jun. 2002). The most current statistics indicate that health care costs have generally stabilized at around 13% of the gross domestic product. *See id.*

<sup>138</sup> The most recent public example of an FDA decision affecting a company's fortunes is likely the rejection of ImClone's cancer drug Erbitux. *See* Nancy Dillon, *Cancer Drug Woes Add to Imclone Ills*, DAILY NEWS, Aug. 20, 2002, at 59.

awards received in litigation can help to alleviate the impact of a mistake, few would argue that money can restore the damage caused by a defective drug.

Therefore, the government's interest in the drug approval process is protecting the public by approving only safe and effective ones. If an error is to occur, it should occur on the side of caution. In other words, if the FDA believed that Phelox *might* cause tremor so as to make the drug's risk-benefit ratio negative, it should have rejected MegaPharma's NDA.

## B. JUDICIAL INTERESTS IN AGENCY DECISIONS

Regardless of the extent of an agency's efforts, mistakes are bound to occur. Invariably, these mistakes will result in litigation that questions the correctness of an agency's decisions. This article now addresses what interests are represented in such litigation.

### 1. Patent Litigation

The most direct impact of patent litigation is on the litigants themselves. In general, one litigant holds a patent and seeks to exclude others from performing infringing acts (*e.g.*, making a product that infringes), while the other litigant contends either that it does not infringe or, relevant to this analysis, that the patent is invalid. The impact on each party is generally financial and can range from a minor inconvenience to a bet-the-company proposition.

The impact is not limited to the litigants, however. In the hypothetical outlined at the start of this article, for example, the availability of a generic version of Phelox would provide a cheaper SSRI to patients or their Health Maintenance Organizations. One need only look at the explosion in pharmaceutical treatment options for depression to see that the introduction of new treatments can have significant societal impact.<sup>139</sup>

Except for rare circumstances, however, most patent litigation, while not entirely separated from daily life, has a limited scope of effect. As a result, the courts' interests are similarly limited. The courts wish to determine whether the patent was properly granted given the state of knowledge at the time. If it

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<sup>139</sup> The first major SSRI, Prozac, has been taken by over 40 million people worldwide, according to its name-brand manufacturer. See Prozac.com, *How Prozac Can Help: Prozac Makes History*, <http://www.prozac.com/index.jsp> (last visited March 27, 2004.).

was properly granted and thus infringed, one party will owe the other party money, and an injunction will likely issue. If the patent is found invalid, the accused infringer can continue their actions, and attorneys' fees *may* be granted to the party proving invalidity. In either case, the result is fundamentally economic.<sup>140</sup> Most inventors believe patents are beneficial, even if that patent *might* later be held invalid. Unless the patent is obtained fraudulently, the danger of having to pay more than attorneys' fees is minor, and even a questionable patent is more beneficial in negotiations than no patent at all. In other words, patent litigation plays a relatively minor role in regulating conduct within the bounds of non-fraudulent behavior before the patent office. Therefore, an inventor is unlikely to not apply for a patent because of a fear that it might later be found invalid.

## 2. Pharmaceutical Tort Litigation

Parties in pharmaceutical tort litigation argue over whether or not the FDA correctly approved a drug. The impact of FDA mistakes may be broader and more emotionally significant. In the case of FDA approval of a drug, a mistake<sup>141</sup> has the potential to affect a great number of consumers. SSRIs, for example, are prescribed to tens of millions of people worldwide every year.<sup>142</sup> This article's hypothetical five percent market share for Phelox would reflect an enormous patient population since litigation over the drug's safety would potentially have an impact on all of them.<sup>143</sup>

Similar to patent litigation, in pharmaceutical tort litigation, a liable defendant pays damages to the plaintiff. There are, however, two important differences between the two types of litigation. First, litigation over pharmaceutical drugs elicits emotion because it involves human life and health. Second, there is a significant industry effect beyond the scope of the individual litigation. Purely compensatory damages paid by a

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<sup>140</sup> This is an oversimplification, but provides a generally accurate overview.

<sup>141</sup> Here the mistake refers to approving a pharmaceutical drug that later proves to be unsafe for consumption.

<sup>142</sup> See *FTC Order Clears Way for \$90 Billion Merger of Pfizer Inc. and Warner-Lambert Company*, available at <http://www.ftc.gov/opa/2000/06/pfizer.htm> (2000) (U.S. sales of SSRI/SNRI [selective norepinephrine reuptake inhibitors] antidepressants total approximately \$7 billion annually).

<sup>143</sup> Five percent of the seven billion dollar market in 2000 is 350 million dollars, which means the total number of customers could easily reach tens of millions. See *id.*

drug manufacturer can rapidly reach to millions of dollars or more if punitive damages are awarded and upheld.<sup>144</sup> Defense costs can easily reach to billions of dollars.<sup>145</sup> It is possible that blockbuster drugs could remain profitable even after massive products liability litigation. However, unlike a patentee's decision with respect to a potentially invalid patent, many drug manufacturers would rather make no drug than an improperly approved drug due to these costs.<sup>146</sup>

Thus, the issues involved in determining whether the FDA made a mistake in approving an unsafe drug are somewhat different than those underlying a USPTO error in issuing a patent. The potential group impacted by the FDA decision is larger, and the impact is more personal. Furthermore, the litigation has a larger potential impact on regulation of industry.

#### IV. THE IMPLICATIONS FOR THE "REGULATORY COMPLIANCE DEFENSE"

This article's hypothetical situation deals with two questions. The first question asks whether or not the USPTO should have issued a patent for Phelox. The second question asks whether or not it was a mistake for the FDA to approve Phelox. Currently, a presumption of validity would likely uphold the issuance of the patent by the USPTO. In the absence of a presumption of safety, however, a jury is likely to find that Phelox was unsafe because its risk-benefit ratio is negative. This article argues that a company that has complied with all relevant FDA regulatory requirements should receive some

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<sup>144</sup>See *State Farm Mutual Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003) (restricting the availability and size of punitive damage awards under the due process clause). "[P]unitive damages should only be awarded if the defendant's culpability, after having paid compensatory damages, is so reprehensible as to warrant the imposition of further sanctions to achieve punishment or deterrence." *Id.* at 1251.

<sup>145</sup>*Up to 90,000 Opt Out of AHP Settlement; 61,000 File Claims*, 6 MEALEY'S LITIG. REP. FEN-PHEN /REDUX 2, 1-2 (2003) (noting that one manufacturer involved in the diet drug litigation has set aside \$14 billion as its reserve for the litigation).

<sup>146</sup>This is at least suggested by the ratio of drugs that make it through the development process. See *supra* note 60 and accompanying text. Of course, certain blockbuster drugs (generally thought of as drugs with annual sales of over a billion dollars) might remain profitable even after massive products liability litigation. In the current environment, this article contends that a profit on any drug with a significant safety problem is unlikely at best. See *supra* note 54.

protection from tort suits like the protection enjoyed by patentees.

Academic discussions of a “regulatory” defense in the tort context have been binary: either FDA compliance should provide immunity with few exceptions<sup>147</sup> or the system should remain largely unchanged with some incremental modifications as to how cases are handled.<sup>148</sup> The discussions also tend to consider regulatory compliance defenses either in a single limited agency context (frequently the FDA), or all together, addressing a wide range of regulatory activities. As outlined throughout this article, the settings of different regulatory proceedings should be considered, and each regulatory context should be considered separately. When this approach is followed in connection with FDA-approved drugs, a third resolution becomes a distinct possibility.

This third resolution is presented after discussion of the two main approaches to a “regulatory defense” in the FDA context, demonstrated by recent articles by Professors Robert Rabin and Richard Stewart.<sup>149</sup> This part examines what lessons can be learned from comparing the FDA context to the USPTO context, and it concludes that the comparison suggests a different treatment for FDA approvals. This different treatment is comparable to the treatment of issued patents with respect to their validity.

#### A. THE POSITION AGAINST PRECLUSION

In the keynote paper of the Georgetown Law Journal symposium, Professor Rabin concluded that the case for a regulatory compliance defense<sup>150</sup> was “an uneasy proposition.”<sup>151</sup> In regard to litigant competency, Rabin wrote that the tort system maintained a role as an “information-generating mechanism

<sup>147</sup> See, e.g., Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System*, 88 GEO. L.J. 2167 (2000) (summarizing the continued soundness of the 1991 American Law Institute Reporter’s Study, Enterprise Responsibility for Personal Injury).

<sup>148</sup> See, e.g., Robert L. Rabin, *Keynote Paper: Reassessing Regulatory Compliance*, 88 GEO. L.J. 2049 (2000) (discussing the proper role of regulatory compliance as a way to limit traditional functions of the tort system).

<sup>149</sup> See *supra* notes 147-48. These articles do not encapsulate the entire range of arguments existing, but are a convenient summary of the most relevant arguments.

<sup>150</sup> The preclusion of a tort suit based on regulatory compliance. Rabin, *supra* note 148.

<sup>151</sup> *Id.* at 2053. Professor Rabin focuses largely on the American Law Institute’s 1991 proposal, discussed *infra* notes 178-82 and accompanying text.

and as a compensatory system.”<sup>152</sup> As for system competency, Professor Rabin first acknowledged that the tort system, in its recent history, has been imperfect in reaching scientifically justifiable conclusions, citing the Bendectin<sup>153</sup> and breast implant litigation.<sup>154</sup> Nonetheless, he noted that the judicial system has made some progress towards ameliorating these problems, generally through strengthening the judicial role as a gatekeeper for expert testimony under *Daubert*<sup>155</sup> and *Kumho Tire*.<sup>156</sup> The judicial system has also made improvements through innovative judicial efforts to obtain unbiased expert opinions, such as Judge Pointer’s expert panel in the breast implant multidistrict litigation.<sup>157</sup>

In addition to the modest improvements in gate-keeping regarding expert testimony<sup>158</sup>, Rabin also considered the importance of the tort system as a means to uncover “bad conduct” – cover-ups, a failure to disclose data to the FDA, inappropriate marketing, and the like. With the FDA relationship fundamentally nonadversarial, there presently exists no agency or group of people besides plaintiffs’ lawyers with an interest in uncovering such wrongdoing.<sup>159</sup> While most proposals for a broad regulatory compliance defense maintain an exception for fraud, Rabin argued that the exception was too narrow.<sup>160</sup> He noted that, for example, alleged fraudulent behavior by tobacco companies was not uncovered by people seeking to prove fraud, but by people seeking to prove negligence in failure to warn. If a broad defense containing a fraud exception were in place, the investigations that uncover fraud would potentially never occur.<sup>161</sup>

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<sup>152</sup> Rabin, *supra* note 148, at 2061.

<sup>153</sup> *Id.* at 2063; *see also* *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993) (plaintiffs suing defendant pharmaceutical company to recover for birth defects allegedly sustained as result of mother’s ingestion of anti-nausea drug Bendectin).

<sup>154</sup> *See* Rabin, *supra* note 148, at 2061-63.

<sup>155</sup> *Daubert*, 509 U.S. at 597 (identifying a judicial “gatekeeper” role in evaluating the validity and reliability of scientific evidence).

<sup>156</sup> *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147-151 (1999) (clarifying that *Daubert* applies to all expert testimony, not just that denominated “scientific,” and also declaring the factors for evaluating proffered opinion testimony identified in *Daubert* as nonexclusive).

<sup>157</sup> *See* Rabin, *supra* note 148, at 2064-68.

<sup>158</sup> *See id.* at 2067-68.

<sup>159</sup> *Id.* at 2069.

<sup>160</sup> *See id.* at 2070.

<sup>161</sup> *See id.*



The second justification for the tort system, according to Rabin, is its role in the enforcement of compensation.<sup>162</sup> He first observed that many of the debates regarding a regulatory defense assume that the standard applied will always be the risk-benefit analysis.<sup>163</sup> However, if a version of California's consumer-expectations theory, which makes the tort system closer to a risk spreading system, is applied, a regulatory defense fits less well.<sup>164</sup> As Rabin observed, a state could rationally decide to make its tort system a means for spreading the risk of harm from pharmaceuticals, even when the drugs are "safe" under a risk-benefit analysis.<sup>165</sup> Using the tort system as this sort of no-fault insurance scheme is not its best use, as Rabin noted.<sup>166</sup> However, it is another factor that points in favor of keeping a role for the tort system.

Lastly, Professor Rabin discussed the implementation of the broad regulatory compliance defense, and contended that it faces numerous real-world problems.<sup>167</sup> Among them is the possibility that the FDA is not "optimally stringent" or absent of political pressure, as well as the danger that the fraud exception would swallow the rule.<sup>168</sup> Finally, and most importantly, Rabin looked at all potential situations that would take place outside of the FDA's careful approval process. Even assuming that the FDA's pre-marketing analysis is optimally stringent, the roles that off-label usage, side effects not appearing in the clinical trials, or over-promotions play must be determined.<sup>169</sup> Alleged injuries resulting from these contexts are commonplace.<sup>170</sup> Therefore, basing a broad defense in those post-marketing cases on the pre-marketing review suggests that a regulatory compliance defense may not prove to be successful.

#### B. THE POSITION FOR PRECLUSION

The foundational document for most arguments in favor of preclusion is the American Law Institute's 1991 Reporter's

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<sup>162</sup> See *id.* at 2071-74.

<sup>163</sup> See *id.*

<sup>164</sup> See *id.* at 2072-73.

<sup>165</sup> See *id.* at 2072-73.

<sup>166</sup> See *id.* at 2073-74.

<sup>167</sup> See *id.* at 2082.

<sup>168</sup> See *id.* at 2076-77.

<sup>169</sup> See *id.* at 2077-82.

<sup>170</sup> See *id.*

Study.<sup>171</sup> The study recommended that “subject to certain carefully tailored conditions and limitations, compliance with regulatory requirements imposed by an administrative agency should preclude tort liability based on negligence.”<sup>172</sup> The former Chief Reporter of the report, Professor Richard Stewart, contributed his defense of the proposal to the symposium referenced above.<sup>173</sup>

The ALI’s (and Stewart’s) proposal provides immunity if (a) the risk was under the control of a “specialized administrative agency” with “statutory authority to monitor and assess risk-creating activities”, and with a “mandate to establish” controls on relevant behavior; (b) the defendant complied with all relevant regulatory requirements; and (c) the defendant disclosed to the agency all material information it has about the risks and their control, including any indication that the agency’s approach might be inadequate.<sup>174</sup> “Tort litigation, in practical effect, amounts to a second, duplicative system of review of the agency’s decision, conducted in accordance with quite different procedures and principles.”<sup>175</sup> In other words, the FDA makes an informed decision with extensive data available, yet juries frequently disregard these data and make decisions that are unsupported by science.

Professor Stewart notes the improvements in the gate-keeping efforts described by Professor Rabin and agrees that they are good ideas.<sup>176</sup> He concludes, however, that the institutional improvements that have begun in the judicial system are stronger evidence that the tort system’s role should be abandoned.<sup>177</sup> He suggests that those improvements are efforts to make the tort system more like the FDA, with more expert involvement and more decisions made by analytical individuals rather than juries.<sup>178</sup> Therefore, he concludes that if the way to

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<sup>171</sup> AMERICAN LAW INSTITUTE, REPORTER’S STUDY, ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY (1991). This Study is not limited to pharmaceuticals.

<sup>172</sup> Stewart, *supra* note 147, at 2167.

<sup>173</sup> See *id.* at 2167 n.1.

<sup>174</sup> See *id.* at 2168. While the ALI proposal would limit the defense in all situations where imposing tort liability, in addition to regulation, is likely counterproductive, the exchange between Rabin and Stewart is focused on the FDA-pharmaceutical context. See *supra* notes 147-48.

<sup>175</sup> Stewart, *supra* note 147, at 2178.

<sup>176</sup> See *id.* at 2177.

<sup>177</sup> See *id.* at 2179.

<sup>178</sup> See *id.*

fix the tort system is to make it like the FDA, the tort system is not needed.<sup>179</sup> “Why reinvent the wheel?”<sup>180</sup>

He then turns to Professor Rabin’s contention that the tort system maintains an important role in information gathering and in compensation schemes. Professor Stewart again concludes that these roles fall short of justifying the current system.<sup>181</sup> As for information gathering, the “ferreting out instances of firms’ nondisclosure,”<sup>182</sup> Professor Stewart first acknowledges that this role is indeed an important aspect of the tort system.<sup>183</sup> However, he contends that the ALI Study proposal was designed precisely to accomplish that goal.<sup>184</sup> In particular, the proposal requires that a defendant “seeking to invoke compliance preclusion” must have “provided the regulatory agency in a timely fashion with all relevant risk information in the defendant’s possession regarding not only the risks associated with its products and processes but also the means of risk control, regardless of whether the regulatory program in question imposes such an obligation.”<sup>185</sup> This requirement would in his view allow plaintiffs’ attorneys to be incentivized to find potential wrongdoing.<sup>186</sup>

As for the compensation role of the tort system, Professor Stewart agrees that compensation may be an important societal goal, given the fact that no drug is risk free. Nonetheless, he contends that the tort system is an exceedingly inferior approach to such compensation, especially compared to programs such as the national vaccine compensation program.<sup>187</sup>

Even if the tort system was the only option for compensation, he rejects Professor Rabin’s argument that it works. First, it requires a strict liability standard, which is not what most states, even those applying the “consumer expectations” test, impose.<sup>188</sup> Rather, a finding of fault under such a test is “tantamount to a determination that the product should never have been marketed,” contrary to the idea of providing compen-

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<sup>179</sup> *See id.*

<sup>180</sup> *Id.*

<sup>181</sup> *See id.* at 2180-81.

<sup>182</sup> *Id.* at 2180.

<sup>183</sup> *See id.* at 2179.

<sup>184</sup> *See id.* at 2180.

<sup>185</sup> *Id.*

<sup>186</sup> *See id.* at 2180-81.

<sup>187</sup> *See id.* at 2181-82.

<sup>188</sup> The consumer expectations test allows jurors to find a product defective if it fails to meet consumers’ expectations of safety. *Id.* at 2183.

sation even for products with a positive risk-benefit ratio.<sup>189</sup> He also notes that the “consumer expectations” test is not applicable to “technically complex” products, presumably including pharmaceuticals.<sup>190</sup> Finally, he points out that the “consumer expectations” test is simply not recognized in many jurisdictions.<sup>191</sup>

Professor Stewart provides a brief discussion of Professor Rabin’s concerns about off-label usage, risks that come up only in the post-marketing time period, and over-promotions.<sup>192</sup> The preclusion Stewart advocates applies only to regulated uses (*i.e.*, not off-label usage).<sup>193</sup> Further, Stewart argues that the disclosure requirement would create an incentive to disclose information about post-marketing risks.<sup>194</sup>

### C. A MIDDLE GROUND: LEARNING FROM THE PATENT CONTEXT

Professors Rabin and Stewart present two different approaches to FDA decisions in tort litigation. Comparing patents and FDA approvals suggests a third way. The treatment of issued patents in validity proceedings can be a model for the treatment of approved pharmaceuticals in tort litigation. This article contends that a policy that presumes safety and efficacy is supported both as a matter of consistency between different agency’s decisions, and as a matter of policy because it resolves or reduces many of the concerns of both Professors Rabin and Stewart.

#### 1. A Presumption of Safety and Efficacy

The factors that should be considered in determining how to implement agency decisions in litigation include the strength of the process at each agency, the interests furthered in litigation, the interests and incentives among the parties involved, and, most generally, the risks of an incorrect decision by the agency. Therefore, when comparing the patent and FDA contexts to decide whether the approach taken with issued patents should be imported to the pharmaceutical tort context, these factors must be evaluated. All but one of these factors support giving FDA decisions at least the deference received by USPTO

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<sup>189</sup> *Id.* at 2183-84.

<sup>190</sup> *Id.* at 2184-85.

<sup>191</sup> *See id.* at 2185.

<sup>192</sup> *See id.* at 2185-86.

<sup>193</sup> *See id.* at 2186.

<sup>194</sup> *See id.*

patent grants.<sup>195</sup> While the evaluation is not merely checking off boxes on a list and counting check marks, a brief summary is helpful.

First, the FDA's review process is as comprehensive as the USPTO's, regardless of the difference in scope of reviewed issues.<sup>196</sup> The questions the FDA is required to answer are certainly more intense, and the process it goes through is more thorough. The presumption of validity is based on approximately twenty hours of consideration by the USPTO, whereas hundreds or thousands of hours, including ongoing post-marketing approval analysis of the risk-benefit ratio, are performed by the FDA.

Second, the FDA's core mission is the protection of public health, while the USPTO's mission is the issuance of patents. This difference in goals may make a difference in results. Generally, the FDA's client is the public, while the USPTO's client is the applicant.<sup>197</sup> The FDA is therefore likely to err on the side of caution more often than the USPTO.

Third, the incentives of the applicants differ. A company seeking approval of a pharmaceutical has incentives not to pursue a drug that may be unsafe. On the other hand, an inventor pursuing a patent that might later be found invalid has few incentives to abandon the application.<sup>198</sup>

On the other hand, the issues at stake in the two contexts do differ. The risks of a wrong decision are broader and more psychologically significant in the context of drugs. An improper approval of a drug can ultimately end in the loss of life.<sup>199</sup> Even with the difference in effects of wrong decisions, the two systems are structured and operated in such a way that the risk of a wrong decision taking place at the FDA is significantly lower than at the USPTO. The systems are appropriately designed to reduce the odds of an unsafe drug making it through the system while spending less effort on the prevention of invalid patents.<sup>200</sup>

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<sup>195</sup> This discussion presumes that the presumption of validity is legitimate in the patent context. As this article discusses above, there are those who believe that it should be narrowed or eliminated, including the FTC. *See supra* notes 115-19 and accompanying text.

<sup>196</sup> *See supra* Part I.C.

<sup>197</sup> *See supra* Part III.A.1-2.

<sup>198</sup> *See supra* Part III.B.1-2. As noted previously, there are incentives to not be dishonest in advocacy, which is where cost-shifting becomes a genuine risk.

<sup>199</sup> *See supra* Part III.B.2.

<sup>200</sup> *See supra* Part I.

With these factors in mind, the disjunction in treatment between approved patents and approved drugs makes little sense. At a minimum, an FDA-approved drug should receive comparable treatment to a patent issued by the USPTO. An analysis of what constitutes comparable treatment follows.

First, recall what rights MegaPharma receives from an issued patent. MegaPharma's patent is presumed valid, and the jury must conclude by clear and convincing evidence that it is not valid in order to overcome the presumption.<sup>201</sup> This presumption exists even when the party claiming invalidity is basing its case on prior art not presented to the USPTO.<sup>202</sup> Thus, if GenerDrugs had one piece of highly relevant but obscure prior art that the patent examiner had never found, GenerDrugs would still be required to overcome the same presumption of validity. The fact-finder could consider a broad range of evidence in making its determination, from prior art not presented, to arguments made with respect to that prior art, and finally to the persuasive power of the statements made in the prosecution history resulting in the patent's issuance.

Treating FDA approval the same way would thus require a broad presumption of safety and efficacy. In other words, the jury would be instructed that once the FDA approved Phelox, it is presumed to be safe and effective. Further, the jury would be told that it must be convinced by clear and convincing evidence that the FDA's decision was wrong. As in the patent context, a broad range of evidence would be relevant to that determination, including any information not presented to the FDA by MegaPharma,<sup>203</sup> and information about risks that arose after the most recent conclusion by the FDA that the drug was safe and effective.<sup>204</sup>

Perhaps more controversially, the presumption would be in place whether or not the complaint involved on-label or off-label usage, or over-promotion. In either case, off-label usage or over-promotion by the defendant would be considered, but,

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<sup>201</sup> See *supra* note 11 and accompanying text.

<sup>202</sup> See 35 U.S.C. §282.

<sup>203</sup> In the patent context, even what would roughly be considered fraud – *e.g.*, the intentional nondisclosure of material prior art – must be proven by clear and convincing evidence in order to render the patent unenforceable. See *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867 (Fed. Cir. 1988).

<sup>204</sup> Recall that the FDA reconsiders its submitted data, including adverse event reports, any time there is an updated package insert in order to determine if the product remains safe and effective.

just as with unconsidered prior art in the patent context, it would not make the presumption inapplicable.<sup>205</sup>

The proposal set forth above may seem a bit sparse in details. It does not include, for example, an exhaustive list of factors to put into jury instructions regarding the presumption, nor does it set forth precisely how such a presumption would be implemented. At this point, the goal of this article is merely to provide a new starting point for a discussion. Moreover, an advantage of a presumption, as opposed to outright preclusion, is that it maintains a great deal of evidentiary flexibility. A pharmaceutical trial implementing this presumption would look very similar to those held today, except for the jury instructions and arguments relating to those instructions.<sup>206</sup>

## 2. Presumption of Safety and Efficacy-Addressing Concerns about the Regulatory Compliance Defense

A rebuttable presumption of safety and efficacy for FDA-approved drugs provides a solution for some of the concerns expressed by Professors Rabin and Stewart. First, the full preclusion urged by Stewart leaves potentially too small an incentive for the investigations that both Rabin and Stewart believe are important. The problem is the one identified by Professor Rabin: much “bad conduct” is only discovered through discovery for more garden-variety torts. Making it somewhat harder to prove negligence will reduce the number of marginal cases where the evidence of a negative risk-benefit ratio is scant, but still permits for successful suits when the FDA simply got it wrong without any bad conduct by the drug’s manufacturer. Those suits will occasionally undercover bad conduct that outside of the tort system would remain hidden.

Second, the increased burden of proof would provide another institutional improvement along with those ongoing im-

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<sup>205</sup> This presumption of safety even in off-label usage is analogous to the fact that even allegations that a patent is unenforceable due to inequitable conduct still must be proved by clear and convincing evidence.

<sup>206</sup> This article’s proposal differs from Texas’s new statute that provides for a limited set of bases for overcoming the presumption. *See supra* notes 123-25 and accompanying text.

The proposal also does not directly address punitive damages. Given this article’s approach – and no obvious source from the patent context from which to analogize – this article does not reach a conclusion about how FDA approval should affect the availability of punitive damages, if at all. The addition of a presumption of safety may well support making FDA approval at least a significant factor in, if not a bar to, the recovery of punitive damages. A full determination will have to wait for another day.

provements discussed by Professor Rabin.<sup>207</sup> If the plaintiff is required to make its case by an increased burden of proof, a judge may be more comfortable in taking the *Daubert* and *Kumho Tire* decisions seriously, and dismissing baseless cases. This increased burden of proof would help give a judge a greater sense of security in connection with appeals as well.

Third, though Professor Stewart's point that the tort system is an imprecise means for providing compensation is sound, to whatever extent its role for compensation is important, this proposal maintains it.

Fourth, the presumption of safety and efficacy maintains a significant incentive for the drug sponsors to keep the FDA fully apprised of data regarding drugs, and to keep the package insert updated. The presumption would be "renewed" each time the FDA renewed its safety and efficacy determination. Furthermore, the company's compliance or noncompliance with data-sharing requirements should be a factor in deciding whether or not to disregard the FDA's conclusions.

Finally, the presumption of safety and efficacy provides the flexibility lacking in outright preclusion. In each case, a judge may determine if the situation is relevant to the presumption, or even provide specific jury instructions on the topic.

## V. CONCLUSION

A presumption of safety and efficacy for FDA-approved pharmaceuticals is supported by comparing the FDA's system to the USPTO's system. It maintains the basic outlines of the current tort system, but requires additional evidence to obtain a recovery. Moreover, it expressly tells the jury that the FDA decision is to be presumed correct. It provides judges with additional power to determine liability before trial and put expert testimony to the test. It maintains the accepted role of the tort system as a public safeguard in the development and marketing of drugs. Finally, it treats determinations of two agencies, the USPTO and FDA, consistently. A presumption of safety and efficacy would allow pharmaceutical regulation and pharmaceutical litigation to work in harmony to promote the safe and efficient development and marketing of pharmaceuticals.

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<sup>207</sup> See *supra* Part IV.A.